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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,410	09/07/2006	Calvin B. Harley	38797-8007.US00 (511/002)	6086
79975	7590	11/12/2008	EXAMINER	
King & Spalding LLP P.O. Box 889 Belmont, CA 94002-0889			NATHAN, SHYAM	
			ART UNIT	PAPER NUMBER
			1611	
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			11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,410	Applicant(s) HARLEY ET AL.	
	Examiner SHYAM NATHAN	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse the species of Formula I, which embodies the compound cycloastragenol that reads on claims 1-3, 5-8, 17-24, in the reply filed on 09/29/2008 is acknowledged. Claims 4 and 10 have been withdrawn. This is the first Office Action on the merits of the claims.

Priority

The earliest U.S. effective filing date afforded the instantly claimed invention is 06/25/2003, the filing date of application 60/482,630.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-3, 5-8, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou (US Pub No. 2003/0108629; Pub Date Jul.12,2003;Filed Jul. 16, 2002) in view of (www.drugs.com/npp/astragalus.html); Found on Oct.20, 2008.

Instant claims 1-3,5-8, 17-19 are drawn to A method for conditioning the skin, comprising: applying topically to the skin a formulation comprising a compound of formula I:

where:

each of X1, X2, and X3 is independently selected from hydroxy, lower alkoxy, lower acyloxy, keto, and a glycoside;

OR1 is selected from hydroxy, lower alkoxy, lower acyloxy, and a glycoside;

wherein any of the hydroxyl groups on said glycoside may be substituted with a further glycoside, lower alkyl, or lower acyl, such that the compound includes a maximum of three glycosides; and

R2 is methyl and represents a double bond between carbons 9 and 11; or, R2 forms, together with carbon 9, a fused cyclopropyl ring, and represents a single bond between carbons 9 and 11. and wherein said formulation further comprises and ingredient selected from the group consisting of an emulsifier, a surfactant, a thickener, a skin emollient, and a lubricant, and an ingredient selected from the group consisting of a preservative, an antioxidant, and an antimicrobial agent.

Wherein, wherein the biological activity of said compound is such that a composition containing the compound at a concentration of 1 µg/ml or less is effective to produce a telomerase activity at least 25% greater than observed in a vehicle control, as measured in a TRAP assay of keratinocyte or fibroblast cells and the biological activity of said compound is such that a composition containing the compound at a concentration of 1 µg/ml or less is effective to produce an amount of cell refluence in a scratch assay of keratinocytes which is at least 25% greater than that seen in untreated or other control cells.

Chou teaches of a herbal composition that comprises Radix Astragali (Root)[0135-0140], which contains a series of cycloartane triterpene glycosides denoted astragalosides I to VII, that are based on the genin cycloastragenol, (www.drugs.com/npp/astragalus.html: Under the chemistry section), which is used in a method that provides a treatment for prostate gland and kidney disorders[0002], which can, also, be used as a method to relieve skin infection[0140] (that includes skin erosion), that can be applied topically to skin[0186] and can be a used in an amount of .365% of the total herbal composition[0156, TABLE III]. The composition, also, comprises herbal fruits such Fructus Schisandrac Chinensis(Wuweizi), which contains antimicrobial/bacterial properties[0146] and Water and alcohol as in a Aqueous/alcohol extracts which would act as a lubricant.[0185]

Comment [s1]: These claims are directed to method claims. You have not discussed how the PA meets your methodology. Your reference is directed to treatment of kidney health.

The Chou reference applies radix astragali root to the skin [0186], but Chou does not specifically teach conditioning of the skin. Although the Chou reference suggests the topical use of the Radix Astragali Root, herbal fruits such as Fructus Schisandrac Chinensis(Wuweizi, and water/alcohol, these compounds and its topical application are not immediately envisaged and therefore the instant rejection is made under obviousness..

However it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by the Chou reference and incorporate a topical formulation because the Chou reference suggests such a formulation [0140]. Regarding the preamble, the instant claims are drawn to conditioning of the skin. The Chou reference suggests applying radix astragali root to the skin [0186], but Chou does not specifically teach conditioning of the skin. However, taking the teachings of the Chou reference, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that applying cyloastragenol (Radix Astragali Root) to the skin would necessarily condition the skin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance provided by Chou and incorporate an Astragali root ,herbal fruits such as Fructus Schisandrac Chinensis(Wuweizi, and water/alcohol in the composition. One would have been motivated to do so since Chou suggests the use of Radix Astragali to relieve skin infection[0140] (that includes skin erosion), herbal fruits such as Fructus Schisandrac Chinensis(Wuweizi), which contains antimicrobial/bacterial properties[0146] and Water and alcohol as in a Aqueous/alcohol

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extracts which would act as a lubricant.[0185] and is ,therefore, within the skill of an artisan to select a given compound depending on the desired effect. Therefore, if a skilled artisan wanted to treat skin erosion or infection, one would have been motivated to utilize an Astragali root, if a skilled artisan wanted anti/microbial/bacterial properties, one would have been motivated to use herbal fruits such as Fructus Schisandrac Chinensis(Wuweizi, and if a skilled artisan wanted a lubricant, one would have been motivated to use Water and alcohol as in a Aqueous/alcohol extracts.

Furthermore, the telomerase activity and cell confluence properties of instant claim 23 and 24 is not explicitly disclosed by the prior art reference of Chou, but would be inherent because the function, property and characteristic of the composition taught by Chou is the same of that of the instant claim."Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chou (US Pub No. 2003/0108629; Pub Date Jul.12,2003;Filed Jul. 16, 2002) in view of (www.drugs.com/npp/astragalus.html; Found on Oct.20, 2008). as applied to claim 1 above, and further in view of Wei et al (U.S Pub. NO. 20020164387; Pub. Date Nov.7,2002).

Instant claims 20-22 are drawn to claim 1, wherein the formulation comprises a skin emollient.

Chou teaches of a herbal composition that comprises Radix Astragali (Root)[0135-0140], which contains a series of cycloartane triterpene glycosides denoted astragalosides I to VII, that are based on the genin cycloastragenol, (www.drugs.com/npp/astragalus.html: Under the chemistry section) Which can be used to relieve skin infection[0140], can be applied topically to skin[0186] and can be a used in an amount of .365% of the total herbal composition[0156, TABLE III]. The composition ,also, comprises herbal fruits such Fructus Schisandrac Chinensis(Wuweizi), which contains antimicrobial/bacterial properties[0146] and Water and alcohol as in a Aqueous/alcohol extracts which would act as a lubricant.[0185] But Chou does not teach of a skin emollient.

Wei et al. teaches of a composition that comprises the astragalus root (radix astragali)[0012] to help promote healing of damage tissues[0036] , that can further comprise oils[0011], which reads on a skin emollient.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have add an oil to the composition because Wei et al teaches that oils may be used for texture or shelf-life enhancement. [0011]

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHYAM NATHAN whose telephone number is (571)270-5753. The examiner can normally be reached on Mon-Thurs 8:30a.m. - 5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SN

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611

